BACITRACIN ZINC, NEOMYCIN SULFATE, AND POLYMYXIN B SULFATE-bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment Henry Schein

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

570-3128 Triple Antibiotic Ointment 0.9 g NDC 0404-0167-50

Active Ingredient

Bacitracin Zinc 400 units

Neomyxin Sulfate 5mg (Equivalent to 3.5mg Neomycin)

Polymyxin B Sulfate 5000 units

Purpose

First Aid Antibiotic

Uses

First aid to help prevent infection in minor cuts, scrapes, and burns

Warnings

For External Use Only

Do not use

- In the eyes or over large areas of the body
- If you are allergic to any of the ingredients
- Longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

Deep or puncture wounds, animal bites, or serious burns

Stop use and ask a doctor if

- The condition persists or gets worse
- A rash or other allergic reaction develops

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Clean the affected area. Apply a small amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with a sterile bandage.

Other Information

- Store at room temperature 15°-30°C (59°-86°F)
- Tamper evident. Do not use if seal is torn, cut, or opened.

Inactive Ingredients

White Petrolatum

Label



Triple Antibiotic Label

BACITRACIN ZINC, NEOMYCIN SULFATE, AND POLYMYXIN B SULFATE bacitracin zinc, neomycin sulfate, and polymyxin b sulfate ointment Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0404-0167

TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RW052I)	BACITRACIN ZINC	400 [iU] in 1 g	
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	5 mg in 1 g	
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII: J2VZ 07J96K)	POLYMYXIN B	5000 [iU] in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
WHITE PETROLATUM (UNII: B6E5W8RQJ4)			

Product Characteristics			
Color		Score	
Shape	FREEFORM	Size	
Flavor		Imprint Code	
Contains			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:0404-0167- 50	1728 in 1 CASE	11/03/2022				
1		144 in 1 BOX					
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product					

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333B	11/03/2022		

Labeler - Henry Schein (012430880)

Registrant - Dynarex (008124539)

Revised: 10/2022 Henry Schein